K093366

NOV 24 2009

510(k) Summary

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Nicholas Condakes
Manager, Regulatory Affairs

Lorraine M. Hanley
Director, Global Regulatory Affairs

C. Device Name

Trade Name:	NMI PICC II
Common/usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS-Long Term Intravascular Therapeutic Catheter 21CFR § 880.5970, Class II

D. Predicate Device(s)

Common/usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS-Long Term Intravascular Therapeutic Catheter
Classification Name:	21 CFR § 880.5970, Class II
Premarket Notification:	K091261, K070002, K021704

E. Device Description

The proposed Peripherally Inserted Central Catheter is a Flexible radiopaque catheter with similar technological characteristics as the predicate devices. It is available in single and multi-lumen configurations with markings along the 55cm shaft length; with extension tube(s) and suture wing for catheter securement; and each lumen is differentiated by a proximally located female luer lock adaptor with valve and colored hubs that indicate lumen size.

F. Intended Use

The proposed device is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

G. Performance Data

Performance testing included *in-vitro* testing in accordance with ISO 10555-1 and ISO 10555-3; high pressure injection flow rates; and valve integrity testing; and biocompatibility evaluation in accordance with ISO 10993-1.

H. Substantial Equivalence

Based on responses to questions posed in FDA's Guidance on the CDRH Premarket Notification Review Program, 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

NOV 24 2009

Ms. Lorraine Hanley
Global Director Regulatory Affairs
Navilyst Medical, Incorporated
26 Forest Street
Marlborough, Massachusetts 01752

Re: K093366
Trade/Device Name: NMI PICC II
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 28, 2009
Received: October 29, 2009

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115.. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K093366

Device Name: NMI PICC II

Indications for Use: For short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

Prescription Use	☒	**And/Or**	**AND/OR Over-The-Counter Use:**	☐
(21 CFR 801 Subpart D)			**(21 CFR 801 Subpart C)**	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093366